X-1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

MOBIUS MEDICAL SYSTEMS, LP	§	
	§	
Plaintiff,	§	
	§	Case No. 4:13-cv-3182
v.	§	
	§	
SUN NUCLEAR CORPORATION	§	
	§	
Defendant.	§	

Affidavit of Dr. Nathan Childress
In Support of
Plaintiff Mobius Medical Systems, LP's Motion for Preliminary Injunction

I, Nathan Childress, Ph.D., declare as follows:

1. My name is Nathan Childress, and I am the founder of Mobius Medical Systems, L.P. ("Mobius") based in Bellaire, Texas. I submit this declaration in support of Mobius's Motion for Preliminary Injunction. I have personal knowledge of the facts contained in this affidavit.

2. I graduated *magna cum laude* from the University of Missouri-Columbia in 2001 with a major in Chemical Engineering and a minor in Mathematics. In 2002, I earned my M.S. degree, also from the University of Missouri-Columbia, in Nuclear Engineering. I earned a Ph.D. from the University of Texas M.D. Anderson Cancer Center—generally regarded as one of the elite medical physics programs in the nation—in 2004 under the supervision of Dr. Isaac Rosen. I am a licensed medical physicist in Texas (No. MP10065) and certified in Therapeutic Radiologic Physics by the American Board of Radiology. Since 2007, I have served as a section editor for the Journal of Applied Clinical Medical Physics. I have been published in several

peer-reviewed journals, and have presented multiple times at industry meetings and conferences. Attached as Attachment 1 to this affidavit is a true and correct copy of my curriculum vitae.

3. I founded Mobius in 2010 as a developer of cutting-edge software used in the field of modern radiation oncology. Radiation oncology involves the treatment and imaging of cancer patients with any form of radiation.

4. DoseLab has been Mobius's most successful product. DoseLab is fast, powerful software used to perform quality assurance (QA) for radiation oncology linear accelerators. DoseLab provides accurate, efficient, and powerful TG-142 QA for any kind of linear accelerator-based technology used in modern radiation oncology including intensity-modulated radiotherapy (IMRT), volumetric modulated arc therapy (VMAT), stereotactic radiosurgery (SRS), and stereotactic body radiation therapy (SBRT).

5. The radiation delivered to a patient for treatment purposes should be within 5% of the prescribed dose. In order to achieve that level of precision, the characteristics of a linear accelerator must not deviate from known baseline values acquired at the time of acceptance and commissioning. Deviations from the baseline values may result in patients receiving suboptimal treatment. QA ensures that the machine administering the radiation is operating properly and that correct dose is being delivered.

6. Attached as X-2 to Mobius Medical Systems, L.P.'s Motion for Preliminary Injunction (the Motion) is a true and correct copy of the American Association of Physicists in Medicine 2009 Task Group 142 Report on the QA of Medical Accelerators ("the TG-142 Report"). Nearly all healthcare institutions and treatment centers in the U.S. and abroad look to the TG-142 Report guidelines to ensure that their radiation treatment and image guidance

machines are working properly. The TG-142 Report has become the *de facto* standard for medical linear accelerator QA.

7. DoseLab gives users the ability to perform critical imaging tests using multiple "phantoms." "Phantoms" are objects made of plastic and metal used to test imaging and treatment systems without having to use actual patients. Phantoms typically possess features that allow clinics and treatments centers to test a specific imaging or treatment parameter in a consistent and reproducible way. Clinics and treatment centers traditionally have a mix of treatment and imaging equipment and since different equipment relies on different phantoms for testing, clinics and treatment centers have a mix of phantoms. DoseLab provides these clinics with the ability to support different phantoms from different manufacturers, which avoids buying multiple phantom-specific software products or relying on a single set of phantoms.

8. Mobius released DoseLab in May 2010.

9. In late 2010, I was approached by Jeff Simon of Sun Nuclear Corporation ("SNC"), who offered to distribute DoseLab. At that time, SNC did not offer a software product that could perform TG-142 QA, like DoseLab. SNC wanted to be DoseLab's exclusive distributor of DoseLab in the United States and internationally.

10. SNC became the exclusive distributor of DoseLab in non-U.S. markets on January 1, 2011 and in the U.S. on March 1, 2011. Attached as X-3 to the Motion is a true and correct copy of the Software Distribution Agreement between Mobius and SNC.

11. In April 2011, Jeff Simon of SNC provided the following sales forecast for DoseLab:

	2011	2012	2013
Global Forecast	31	55	75
Domestic Revenues	$ 166,687	$ 295,735	$ 403,275
Domestic Costs	$ 131,595	$ 233,475	$ 318,375
INTL Revenues	$ 197,393	$ 350,213	$ 477,563

INTL Costs	$ 157,914	$ 280,170	$ 382,050
Total SNC Revenues	$ 364,080	$ 645,948	$ 880,838
Total SNC Costs	$ 289,509	$ 513,645	$ 700,425

Actual DoseLab licenses for the same years were:

	2011	2012	2013
Actual Licenses	60	185	>104
Total Revenues (based on MSRP)	$ 572,919	$ 3,000,022	$ > 2,000,000

12. Mobius employees were present at the SNC booth at the industry's AAPM conference in 2011. More visitors to the booth were interested in DoseLab than nearly any other product offered by SNC. This prompted SNC's founder and former CEO, William Simon, to say afterwards to me, "You beat us."

13. On March 8, 2013, Jeff Simon called to tell me that SNC was terminating the distribution agreement. He did not give a specific reason. I was very surprised. DoseLab sales had exceeded expectations, and the parties' business relationship appeared strong. We routinely fielded questions from SNC's sales people and presented DoseLab to prospective customers via webinars hosted by SNC. Mobius employees, including me, assisted in the development of a group of phantoms to be used along with DoseLab.

14. Attached as X-4 to the Motion is a true and correct copy of the Transition Agreement between Mobius and SNC.

15. On March 27, 2013, Mobius received a request from its support portal on www.doselab.com from SNC employee Sindhu Gangisetty stating "I need doselab pro 6.5 version for download. thanks." Upon receiving the request, I researched the employee's role at SNC. Her LinkedIn page said the following:

Software Test Engineer
Sun Nuclear Corporation
March 2013 – Present (1 month)Melbourne, Florida Area

Performing testing on some features of ImageCheck web application, a tool for performing QA activities on Linear Accelerators, which are used to deliver accurate dosage of radiation therapy (chemotherapy) to cancer patients. the goal of the tools is to maximize beam intensity and energy on cancerous cells and minimize the energy on healthy cells.
Microsoft Team Foundation Server - Test Manager, Visual Studio 2012, Design Acceptance Test Plans, Test cases, VMware Workstation 9.
Domain: Image Guided Radiation Therapy (IGRT), LINAC (Linear Accelerator).
Env: Agile development, Scrum.
Training on ISO 13485:2003 Standard.

16. The same day, I responded to Ms. Gangisetty's request with an email asking "What do you need DoseLab 6.5 for?" She responded that she was "interested in the latest features of DoseLab pro 6.5." I replied and copied Jeff Simon. In my reply, I reminded Ms. Gangisetty that SNC does not have permission for DoseLab to be installed anywhere at Sun Nuclear for anything other than sales demonstration purposes. Mr. Simon emailed back saying, "I do not personally understand what happened here but suspect it was harmless curiosity."

17. In a separate message to Mr. Simon, I reminded him that DoseLab is to be used "only by salespeople for the purposes of selling DoseLab" and that "DoseLab is not to be used as a demo product for your software teams, nor is it to be used as a tool to guide development of any Sun Nuclear Products." In his response to me, Mr. Simon said, "This associate is new and was trying to learn about the industry. She should not have contacted Mobius, and I suspect she contacted other companies too out of curiosity."

18. kV/MV imaging QA is performed to ensure that the treatment machine is capable of aligning patients in the correct position before radiation delivery. kV/MV imaging itself is often performed on patients before each treatment. In order to enhance the efficiency and efficacy of this process, DoseLab invented a new algorithm to perform kV/MV imaging quality

assurance analysis of multiple types of phantoms. DoseLab's algorithm and ability to analyze multiple phantoms from multiple manufacturers serves as one of DoseLab's strongest selling points. Indeed, at the time SNC entered the Distribution Agreement with Mobius, DoseLab was the only imaging QA program that could analyze multiple types of phantoms.

19. As part of its exclusive kV/MV imaging algorithm, DoseLab uses reference images to overlay red numbered boxes representing various regions of interest (ROI). No other software uses reference images as an input to its imaging QA algorithm. DoseLab also generates very specific results criteria, including scaling discrepancy, minimum uniformity, X positioning offset, and Y positioning offset. No other software uses these results criteria. ImagePro's default ROI coordinates are identical to DoseLab's to at least three significant digits. DoseLab's interface displays coordinates to only *two* significant digits.

20. A multi-leaf collimator (MLC) is a device made of thick metal leaves that move to dynamically shape a radiation treatment beam. Every leaf is monitored 20-100 times per second. A recording of the leaf positions is called an MLC Log. MLC QA is essential to all clinics that use MLCs because MLC performance defines how precisely radiation is delivered to a patient.

21. Mobius designed an innovative graphical leaf representation using red, yellow, and green rectangles and informative mouse-over tooltips to reflect the results of the MLC log. All DoseLab MLC results, configuration parameters, and methods for visualizing and displaying those results and parameters are found in no other product – except ImagePro.

22. Another method of MLC QA is the MLC strip test, which the TG-142 Report recommends be done weekly. During an MLC strip test, an image is taken by aligning the MLC's leaves to form a series of strips. The image is analyzed to determine each leaf's

deviation from center. DoseLab's method of displaying horizontal lines to indicate individual leaf location and vertical lines to indicate the center of best fit on the evaluated image is a method used by no other QA software. DoseLab's method of displaying the histogram representing differences of the individual leaves is also unique to DoseLab.

23. Cone beam CT imaging provides a wealth of data regarding the proper alignment of a patient to a treatment beam. Accurately positioning patients based on their internal anatomy (bones, organs, etc.) is critical to safe and effective treatment. Thus, most new treatment machines include integrated CT imaging capabilities. Like kV/MV imaging, CT imaging QA uses phantoms, but a CT image consists of 5–200 individual images taken of different slices in a phantom.

24. DoseLab employs a distinct method for displaying Cone Beam CT Imaging. DoseLab uses a distinct numbering scheme, distinct number of ROIs, distinct color-schemes and shapes for identifying certain ROIs, and distinct results parameters that correspond to the scaling discrepancy, minimum uniformity, and geometric distortion.

25. A starshot image is taken by delivering a very narrow strip of radiation, rotating a component of the delivery system, and taking a new image. The sum of these images creates a starshot pattern.

26. Attached as X-5 to the Motion is a true and correct copy of the ImagePro datasheet available at SNC's website, http://www.sunnuclear.com, until on or about November 5, 2013. On or about November 5, 2013, SNC replaced the datasheet attached as X-5 with the version currently found at http://www.sunnuclear.com/documents/ImagePro.pdf. The only material change in the latest version is the removal of DoseLab's Starshot image.

27. DoseLab transmits a message to Mobius's webserver to check for updates each time a licensee launches the software. Mobius's webserver logs these messages, the license name, and the internet protocol address ("IP address") of the message's origin. Between January 2013 and September 2013, Mobius's webserver logged nearly 750 messages from SNC's Brevard County, Florida-based IP address. For reference, Mobius logged less than ten messages per individual DoseLab trial user during the same period. For further reference, two Houston-area treatment facilities with four active linear accelerators together sent only 92 messages in the same 9-month period.

28. To perform monthly TG-142 QA, DoseLab requires a physicist to acquire 15 images. The closest competing product, Standard Imaging's "PIPSpro" product, requires acquiring 26 images. PIPSpro likewise requires eight phantoms for monthly QA to DoseLab's five. ImagePro needs exactly 15 images and five phantoms, the same as DoseLab.

29. Until December 2012, SNC provided monthly lead reports that listed each clinic or treatment center in the DoseLab sales pipeline. Mobius has received no other lead reports since December 2012. Without this customer information, Mobius cannot contact potential customers to present DoseLab. This is particularly damaging if they do not fulfill their DoseLab sales quota for 2013.

30. On September 10, 2013, DoseLab could no longer be found on SNC's website. SNC refused to allow Mobius employees into its booths at the 2013 Meeting of the American Association of Physicists in Medicine (AAPM) and the 2013 American Society for Radiation Oncology Conference.

31. On September 16, 2013, Mobius's COO Stan Eshelman received an email from a potential licensee whose institution needed DoseLab quickly and had already approved the

purchase of DoseLab. The licensee's email indicated that SNC approached the licensee for an opportunity to demonstrate ImagePro prior to their DoseLab installation.

32. On September 17, 2013, Mr. Eshelman received a call from one potential DoseLab licensee inquiring about DoseLab. When potential licensee talked to SNC, SNC told him that SNC no longer sold DoseLab. According to the customer, SNC tried to sell him ImagePro.

33. On September 19, 2013, SNC hosted an ImagePro webinar on the internet. A Houston, Texas-based medical physicist, Andrew Soderstrom, presented the webinar. In response to a question about which product, DoseLab or ImagePro, he would recommend, the presenter said, "ImagePro is not part of DoseLab at this point. … Being that they're both Sun Nuclear devices, it would be my impression, or my assumption, that they will kind of pull in more of the functionality of DoseLab into the IDD as the software and hardware become a little bit more developed." IDD is the physical equipment on which ImagePro is loaded.

34. I attended the recent meeting of the American Society for Radiation Oncology (ASTRO), held from September 22–24 in Atlanta, Georgia. SNC had a booth at the meeting. According to one DoseLab customer, when he approached SNC employees at SNC's booth to discuss renewing his DoseLab maintenance agreement, SNC tried to sell him ImagePro instead.

35. On September 25, 2013, Mr. Eshelman received a call from a DoseLab licensee asking about his DoseLab maintenance renewal. This licensee purchased a DoseLab license in 2013 with a maintenance package valid until 2015. According to this licensee, SNC Service Contract Manager John Archipolo contacted him regarding another TG-142 QA product, ImagePro, even though his DoseLab license would not expire for nearly 18 months. Mr. Archipolo pitched ImagePro as an "upgrade" to DoseLab and offered the licensee "a

maintenance software upgrade path." Additionally, the licensee was unsure whether DoseLab would be continued to be supported at all.

36. On October 1, 2013, SNC regional account manager Stacey Geier contacted a DoseLab licensee awaiting final approval from his institution. According to the licensee, Ms. Geier attempted to get the licensee to cancel his DoseLab purchase in favor of an ImagePro purchase by claiming that DoseLab had some "deficiencies" and suggesting that DoseLab may not be compatible with future SNC products.

37. On October 1, 2013, Mobius Account Manager Mickey Martin received an email from a DoseLab licensee asking if Mobius still supports DoseLab. According to the licensee, SNC told him that SNC no longer supports DoseLab.

38. An institution or treatment center often will purchase from SNC a set of phantoms and DoseLab at the same time. In the past, SNC shipped the software and the phantoms together. On October 2, 2013, a DoseLab licensee emailed Mobius asking why he had not received DoseLab in the same box as his phantoms, as expected. Mobius has no record of this licensee's purchase. His September 6, 2013 purchase receipt indicates a shipping date of September 26, 2016 for DoseLab.

39. On October 29, 2013, one of Mobius's salespeople received a phone call from a Mobius customer with a pending DoseLab purchase order via SNC. According to this customer, SNC was trying to get him to do an ImagePro "swap" for his institutionally-approved DoseLab purchase.

40. Access to the DoseLab source code is heavily restricted and those few employees with access are subject to confidentiality obligations. All employees have a duty to maintain the confidentiality of DoseLab's most inner workings. Mobius does not freely provide DoseLab for

download, and even demonstration licenses require potential customers to obtain log-in credentials and a trial license that likewise limits use and protects confidentiality. Even after receiving the software, a user must accept an end-user license agreement, which precludes improper use, such as reverse engineering.

41. I do not have detailed time records of my work on DoseLab, but I considered it to be my full-time job, and often spent more than 80 hours per week on its development. Since DoseLab's initial release in 2010, the Mobius development team and I have spent countless hours adding features and refining its functionality. No one at SNC participated in this development effort.

42. In 2012, DoseLab accounted for **96%** of Mobius's income, and in 2013 to date, DoseLab has contributed **79%** of Mobius's income. In addition to direct revenue, there are years (10 years is not uncommon) of maintenance renewal package fees (15% of MSRP each year). In addition to that, satisfied DoseLab customers are more likely to license Mobius's other products. Accordingly, losing a DoseLab customer has serious repercussions in the years to come, both with maintenance fees and synergy in selling other products.

Executed this 7th day of November, 2013, at Houston, Texas.

Dr. Nathan Childress

Sworn to and subscribed before me on this 7th day of November, 2013, at Houston, Harris County, Texas.

SANDRA L. WILKINSON
Notary Public, State of Texas
Commission Expires 10-29-2016

Notary Public, State of Texas

Attachment 1

NATHAN L. CHILDRESS, PH.D., DABR

nathan@mobiusmed.com

WORK EXPERIENCE

Founder, Mobius Medical Systems, LP, May 2010 – present.
Developed DoseLab TG142, DoseLab Pro, FractionCHECK, Mobius3D, and MobiusFX radiation oncology quality assurance software suites for clinical use in most international markets. Obtained ISO 13485 certifiation, and maintain compliance with all IEC 62304 guidelines.

Instructor, Baylor College of Medicine, September 2004 – May 2010.
Experience with new linac commissioning (Varian 6EX, Varian 21iX), IGRT commissioning and implementation (Varian 21iX), SBRT commissioning and implementation, IMRT and conventional treatment planning system commissioning (CORVUS and Pinnacle^3), implementing dose verification software (RadCalc) for multiple clinics, external beam and HDR shielding design, total body irradiation, external beam treatments (Varian 21EX, Siemens Primus, Siemens KD, and TomoTherapy), LDR brachytherapy (prostate implants with VariSeed, T+O and gold implants with Pinnacle^3), HDR brachytherapy (Mammosite, endobronchial, and vaginal cylinder treatmetns with Varian VariSource and BrachyVision), Mosaiq system management, intravascular brachytherapy (Novoste Beta-Cath), SBRT planning (Novalis), and Argus QA software. Assisted with the oversight of the dosimetry and therapist groups, including performance evaluations, creating rotation schedules, and developing an online documentation program. Assisted with the transition to a fully paperless department through implementing electronic medical records for all aspects of patient treatments and staff communication.

Software and Web Developer, DoseLab.com and MedPhysFiles.com, 2003 – present.
Designed and support several open-source programs, including DoseLab (over 1,000 active clinical and research sites), HDR secondary calculation (over 500 clinical users), a compilation of radiation dose organ tolerances (downloaded over 4,000 times), and the MedPhysFiles website (over 40,000 files freely distributed).

EDUCATION

Ph.D., Medical Physics, The University of Texas M. D. Anderson Cancer Center, September 2004. Dissertation: *The Design and Evaluation of a 2D Dose Verification System for Intensity Modulated Radiotherapy*. 3.75 GPA. Implemented a novel radiographic film calibration technique, performed extensive Kodak EDR2 film characterization tests, and designed radiation dose verification software (DoseLab). Advisor: Dr. Isaac Rosen.

M.S., Nuclear Engineering, specialty in Medical Physics, University of Missouri-Columbia, January 2002. Thesis: *MCNP analysis and optimization of a triple crystal phoswich detector*. 4.0 GPA. Advisor: Dr. William Miller.

B.S., Chemical Engineering, minor in Mathematics, Honor's degree, Magna Cum Laude, University of Missouri-Columbia, December 2001. 3.85 GPA.

CERTIFICATIONS

- The American Board of Radiology – certified in Therapeutic Radiologic Physics.
- Texas licensed medical physicist – MP10065.

PROFESSIONAL AFFILIATIONS

- Section Editor, Journal of Applied Clinical Medical Physics, 2007 – present.
- Member, AAPM Website Editorial Board, 2007 – present.
- Member, American Association of Physicists in Medicine (AAPM), 2002 – present.

FELLOWSHIPS, AWARDS AND HONORS

- American Legion Auxiliary Fellowship, October 2002 – September 2004.
- Graduate School of Biomedical Sciences Dean's Scholarship, August 2001 – September 2004.
- Selected for the Department of Energy Health Physics Fellowship, May 2001.
- University of Missouri G. Ellsworth Huggins Fellowship, May 1999.

PUBLICATIONS

- S.F. Kry, J. Jones, N. Childress, "Implementation and Evaluation of an End-to-End IGRT Test," Journal of Applied Clinical Medical Medical Physics **13** (2012).
- *N. Childress*, R.A. White, C. Bloch, M. Salehpour, L. Dong, I. Rosen, "Retrospective Analysis of 2D Patient-Specific IMRT Verifications," Medical Physics **32**, 838-850 (2005).
- *N. Childress*, M. Salehpour, L. Dong, C. Bloch, R.A. White, I. Rosen, "Dosimetric Accuracy of Kodak EDR2 Film for IMRT Verifications," Medical Physics **32**, 539-548 (2005).
- *N. Childress*, C. Bloch, R.A. White, M. Salehpour, I. Rosen, "Detection of IMRT Delivery Errors Using a Quantitative 2D Dosimetric Verification System," Medical Physics **32**, 153-162 (2005).
- I. Rosen, H. Liu, *N. Childress*, Z. Liao, "Interactively Exploring Optimized Treatment Plans," International Journal of Radiation Oncology Biology Physics **61**, 570-582 (2005).
- *N. Childress*, I. Rosen, "Effects of Processing Delay on EDR2 Film Absolute Response," Medical Physics **31**, 2284-2288 (2004).
- *N. Childress*, I. Rosen, "The Design and Testing of Novel Clinical Parameters for Dose Comparison," International Journal of Radiation Oncology Biology Physics **56**, 1464-1479 (2003).
- *N. Childress*, L. Dong, I. Rosen, "Rapid radiographic film calibration for IMRT verification using automated MLC fields," Medical Physics **29**, 2384-2390 (2002).
- *N. Childress*, W. Miller, "MCNP Analysis and Optimization of a Triple Crystal Phoswich Detector," Nuclear Instruments and Methods in Physics Research Section A **490**, 263-270 (2002).

LECTURES AND PRESENTATIONS

- *N. Childress*, I. Rosen, "Effect of Processing Time Delay On the Dose Response of Kodak EDR2 Film," 2004 American Association of Physicists in Medicine Annual Meeting oral presentation.
- *N. Childress*, I. Rosen, "Automatic Detection of IMRT Delivery Errors Using a Quantitative 2D Dosimetric Verification System," 2004 American Association of Physicists in Medicine Annual Meeting oral presentation.
- *N. Childress*, "Clinical Implementation of DoseLab Software," The University of Texas Southwestern Medical Center at Dallas, June 2004, invited lecture.
- *N. Childress*, "An Introduction to Patient-Specific IMRT Film QA," The University of Texas M. D. Anderson Cancer Center Intensity Modulated Radiotherapy short course, April 2003 and September 2003, invited lecture.
- *N. Childress*, I. Rosen, "The Design and Testing of Novel Clinical Parameters for Dose Comparison," 2003 American Association of Physicists in Medicine Annual Meeting poster exhibition.
- *N. Childress*, I. Rosen, "Clinical Experience with Kodak EDR2 Film for Patient-Specific IMRT Quality Assurance," 2003 American Association of Physicists in Medicine Annual Meeting poster exhibition.
- *N. Childress*, I. Rosen, "An Introduction to NAT values and the NAT Index for 2D Dose Comparisons," Fall 2002 Southwest American Association of Physicists in Medicine Meeting Young Investigators oral presentation.
- *N. Childress*, L. Dong, I. Rosen, "Rapid Radiographic Film Calibration for IMRT Verification Using Automated MLC Fields," 2002 American Association of Physicists in Medicine Annual Meeting oral presentation.

REFERENCES

Available upon request